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Chemical Safety Assessment and Report

"Guidance on Information Requirements and Chemical Safety Assessment"

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REACH Workshop: Final countdown

14 April 2008, Brussels

Overview - issues

- Starting point: **REACH Registration**
- Generation of information
- Control of risks
- Documentation
- Downstream User (DU) perspective and supply chain communication
- Guidance and supporting IT tools

Registration

AIM:

➔ manufacturers and importers obtain information on their substances and

➔ use this knowledge to enable well-informed management of the risks these substances may present throughout their life cycle

Registration Dossier = Documentation

➔ Technical Dossier: starting at 1 tonnes per year

➔ Chemical Safety Report: starting at 10 tonnes per year

No formal acceptance - industry retain responsibility

Aims of the Chemical Safety Assessment process

- Collect/generate/assess information on uses, exposures and intrinsic properties. Based on this:
- Identify the conditions under which the risks arising from manufacture and use(s) of a substance are controlled.
- Prepare a set of corresponding information on operational conditions and risk management measures (= Exposure Scenarios) to be communicated to the users of the substance (for dangerous substances).
- Document the assessment in a Chemical Safety Report (CSR) for the companies' own documentation.
- Submit CSR to the authorities as part of the registration.

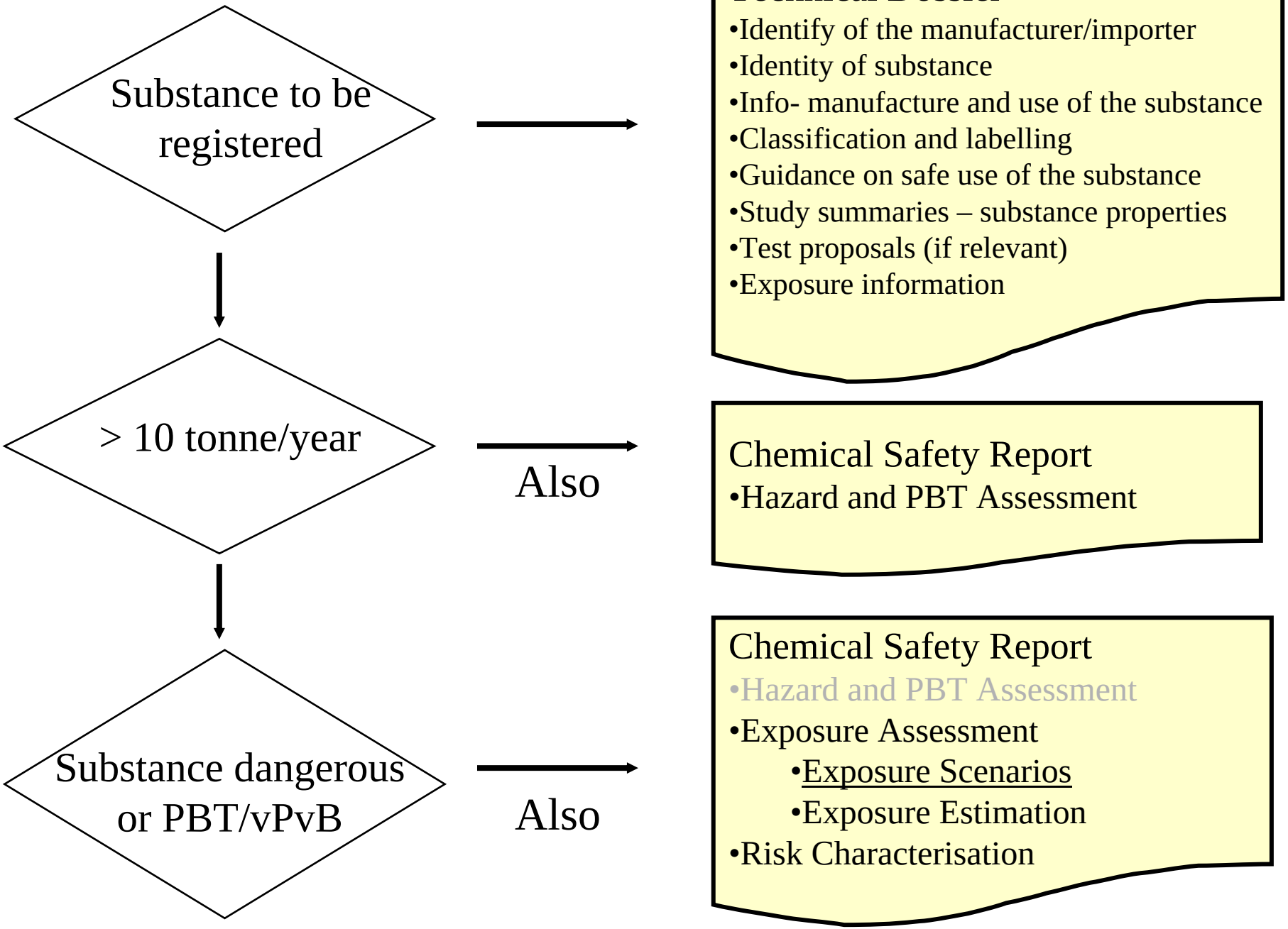
What is the Chemical Safety Report (CSR) ?

- The CSR is the documentation of the Chemical Safety Assessment (REACH Annex I) covering:
  - Hazard Assessment of the inherent properties
    - Human Health
    - Physicochemical
    - Environmental
  - PBT and vPvB assessment*
- and when substance is dangerous or PBT/vPvB
  - Development of Exposure Scenarios for controlling risks
  - Exposure estimation quantifying human and environmental exposure levels
  - Risk Characterisation

* PBT: Persistent, Bio-accumulative and Toxic

* vPvB: very Persistent and very Bio-accumulative

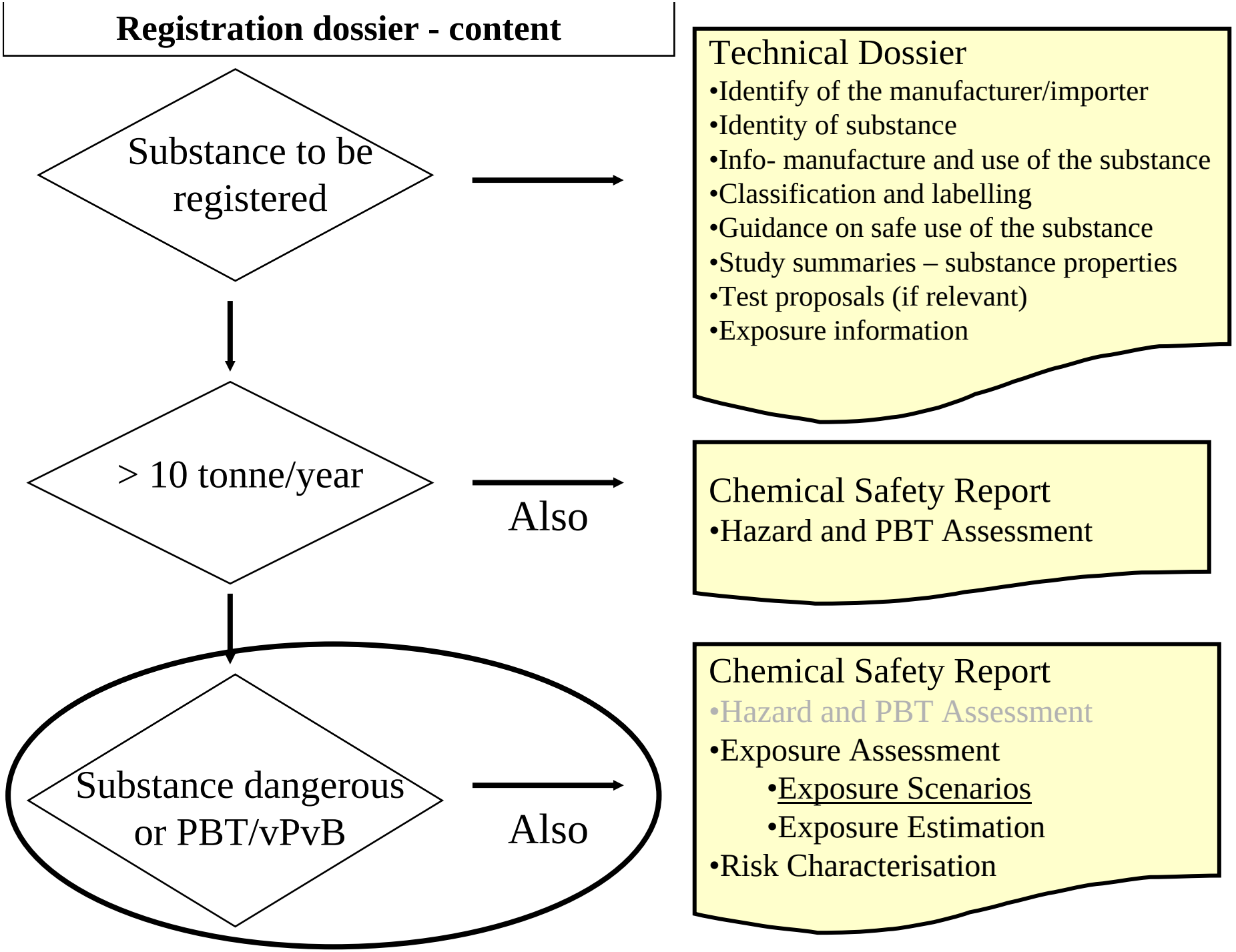
Registration dossier - content



Generation of information on intrinsic properties Hazard and PBT assessment

- Generation of information on inherent properties
  - Collect *all available* information
  - Compare with standard information requirements (tonnage dependant) and identify information gaps
    - Consider adaptations (triggering or waiving of test)
  - Generate further information or make a testing proposal
- Hazard Assessment
  - Classification and labelling (C&L)
  - Dose/concentration-response; No-effect levels (Derived or Predicted no-effect levels/concentrations DNELs/PNECs) or other measure of potency
- Assess whether substance has PBT or vPvB properties

Registration dossier - content



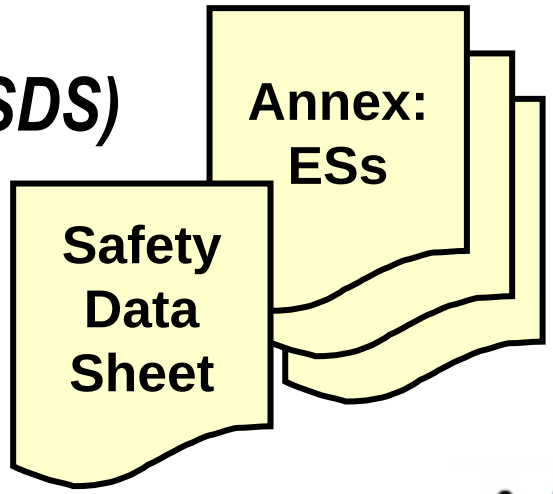
What is an Exposure Scenario (ES) ?

- Conditions for use:
  - Process description
  - Operational conditions (incl. quantity used, frequency and duration of specified operations)
  - Risk Management Measures
    - process control (e.g. closed system and local exhaust)
    - emission control
    - personal protective equipment
    - good hygiene / working practise
    - etc.
- Other relevant information

How will the user know?

Exposure Scenarios will be attached to the Safety Data Sheet (SDS)

-> ***Extended Safety Data Sheets (e-SDS)***



Exposure Scenario Content/Template

Title and covered activities	
1	Short title of the exposure scenario
2	Processes and activities covered
Operational Conditions	
3	Duration and frequency of use
4.1	Physical form of substance or preparation;
4.2	Concentration of substance in preparation or article
4.3	Amount used per time or activity
5	Other relevant operational conditions of use
Risk Management Measures	
6.1	Risk management related to human health (workers, consumers)
6.2	Risk management measures related to the environment
7	Waste management measures
Reference to exposure prediction	
8	Exposure prediction and reference to its source
9	Guidance to DU to check whether he is working within ES

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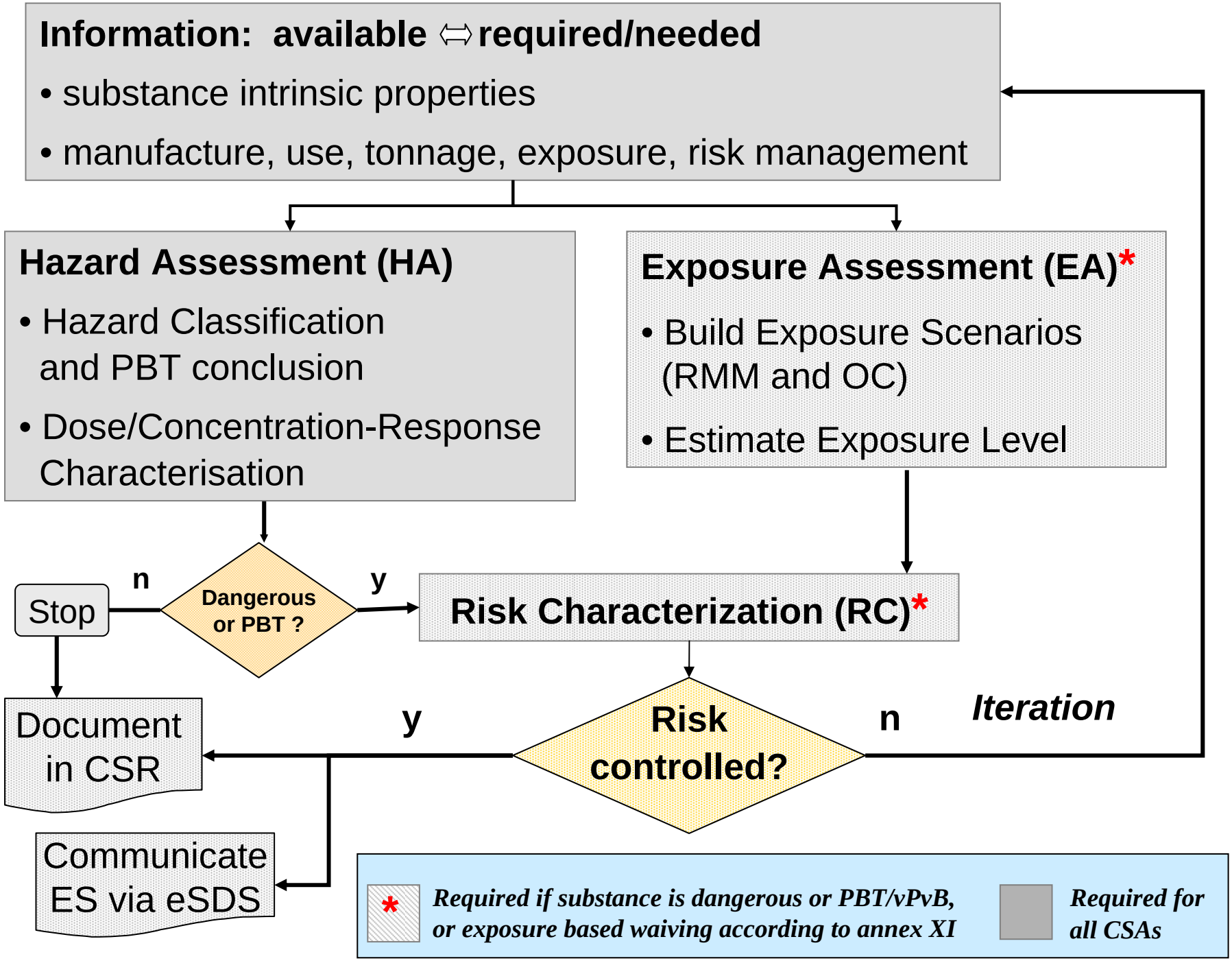
Overview of CSA process


Information: available ⇔ required/needed
• substance intrinsic properties
• manufacture, use, tonnage, exposure, risk management
Hazard Assessment (HA)
• Hazard Classification and PBT conclusion
• Dose/Concentration-Response Characterisation
Exposure Assessment (EA)*
• Build Exposure Scenarios (RMM and OC)
• Estimate Exposure Level
Stop
n
Dangerous or PBT ?
y
Risk Characterization (RC)*
Document in CSR
y
Risk controlled?
n
Iteration
Communicate ES via eSDS
* Required if substance is dangerous or PBT/vPvB, or exposure based waiving according to annex XI
Required for all CSAs

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Exposure Scenarios from the Downstream User point of view

The Downstream User

Must:

- Implement Operational Conditions and Risk Management Measures communicated to him via the exposure scenarios in the SDS Annex
- If he uses the chemical outside the conditions described in the exposure scenario(s)
  - Inform his supplier of this use to make it an identified use
  - Alternatively:
    - Conduct a safety assessment for his own use (and for his downstream uses if he is a supplier)
      - and implement ES from own safety assessment
      - and report to the Agency
    - Switch to another supplier
- Communicate further down the supply chain if he is supplier

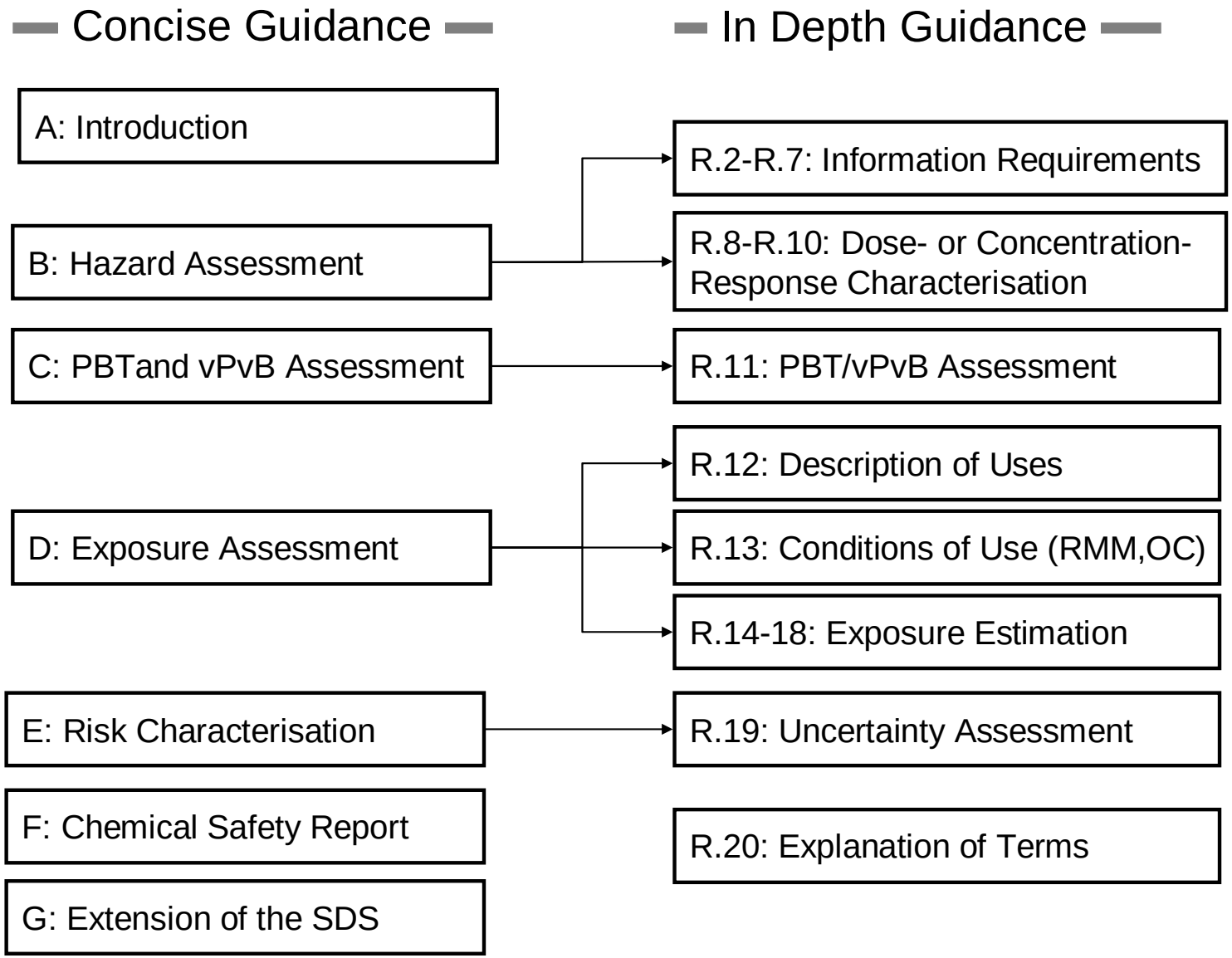
Guidance

- Guidance on Information Requirements and Chemical Safety Assessment (first version to be published on the ECHA web-site before 1 June 2008)
  - Guidance was, between others, developed based on an array of exposure scenario case studies conducted by industry organisations and companies
  - Chemicals industry (CEFIC in cooperation with downstream user organisations) is working on making exposure scenarios examples based on the case studies available
  - Risk Management Measures (RMM) library developed as part of the guidance development project is made available via the CEFIC web-site
- Guidance on Downstream User requirements (available via the ECHA web-site)

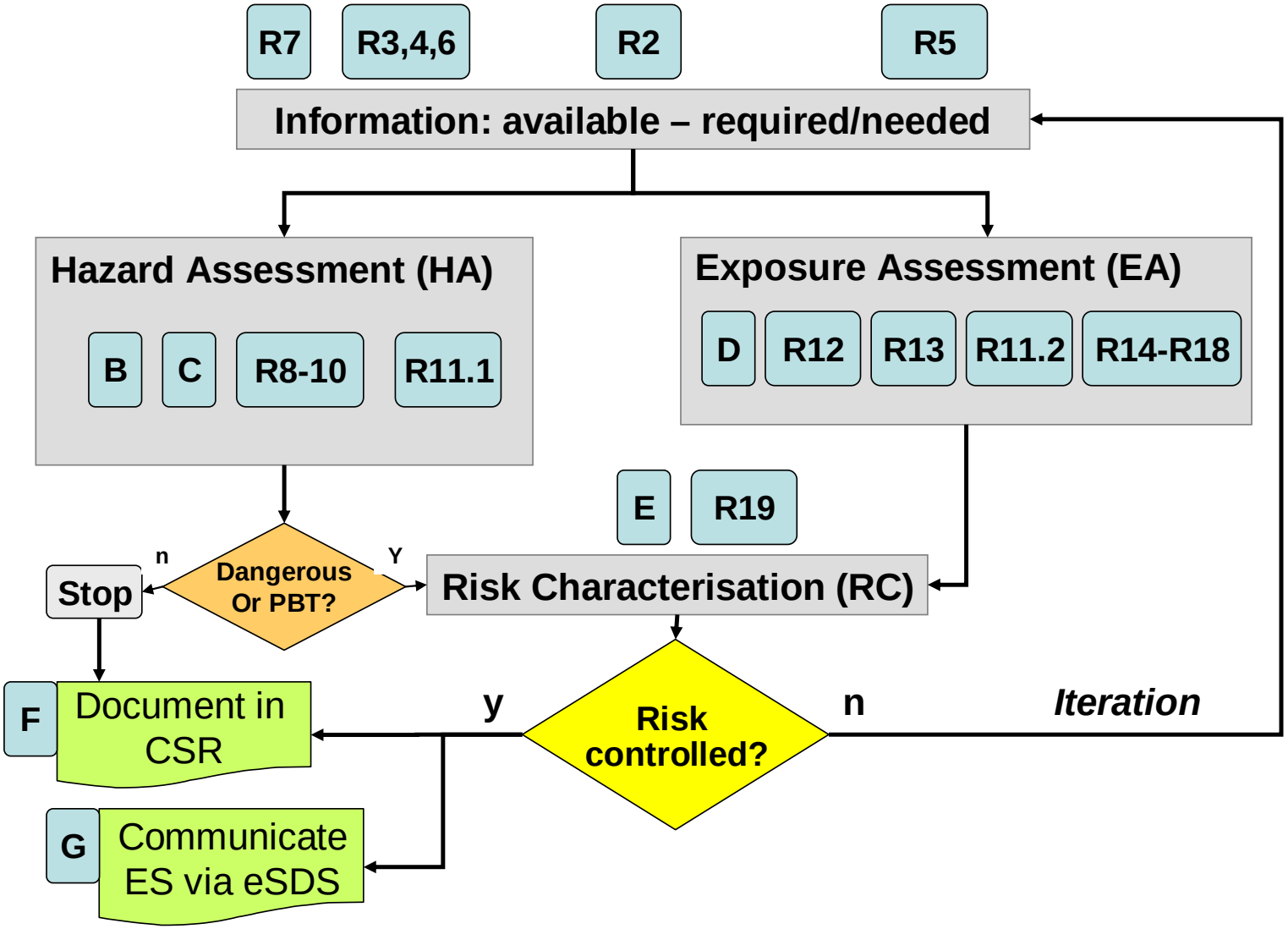
Who will use the CSA Guidance ?

- Manufacturers of substances > 10 t/a
- Importers of substances (> 10 t/a) as such (or as part of preparations)
- Downstream users who need or want to make their own chemical safety assessment
- Producers and importers of articles when they have to register substances intended to be released
- Manufacturers, importers and downstream users preparing or updating a CSA/CSR as part of applying for an authorisation
- Authorities using the Guidance as a reference for activities related to assessment and control of risks under evaluation, authorisation or restriction procedure.

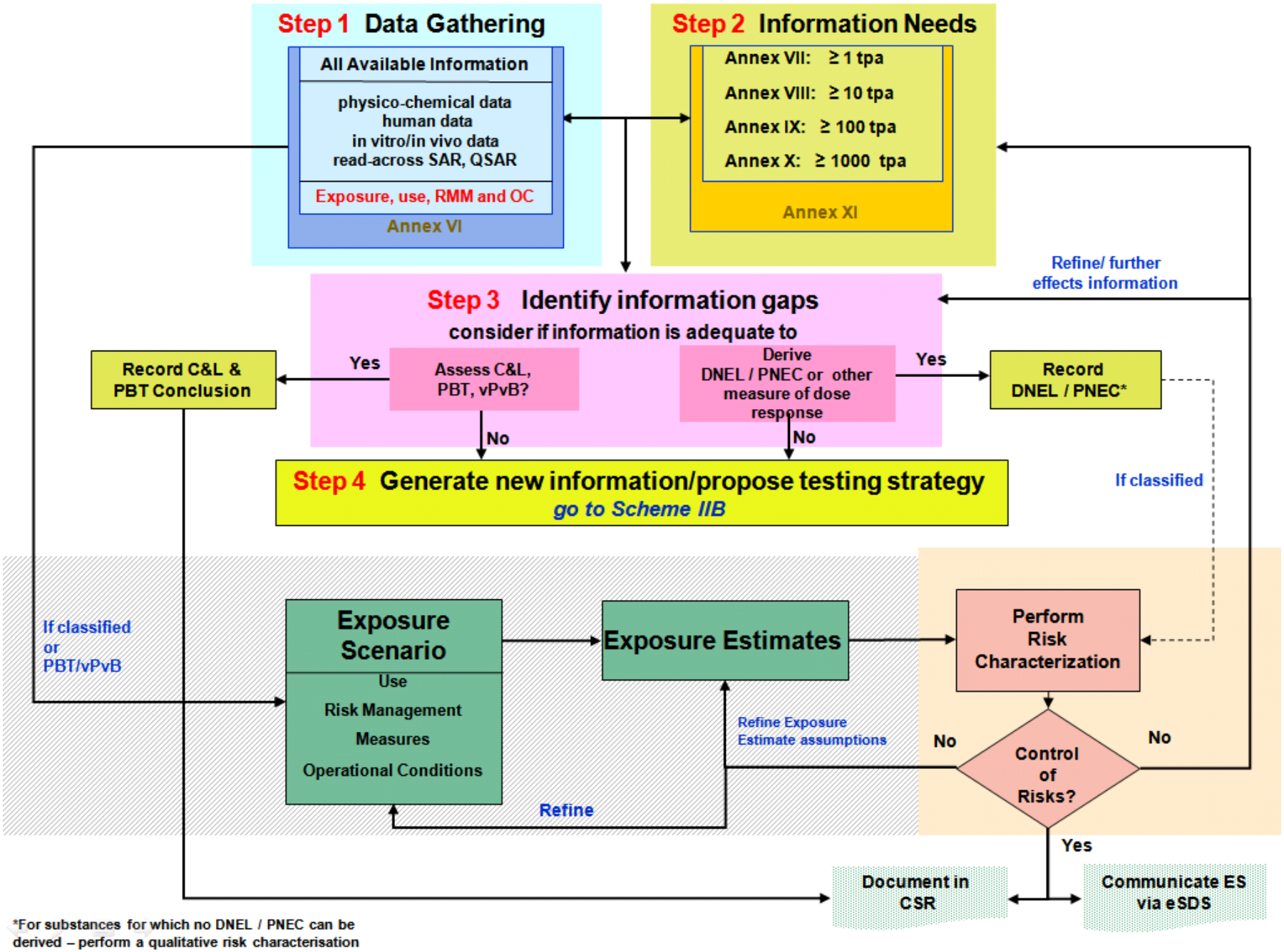
Guidance on Information Requirements and Chemical Safety Assessment



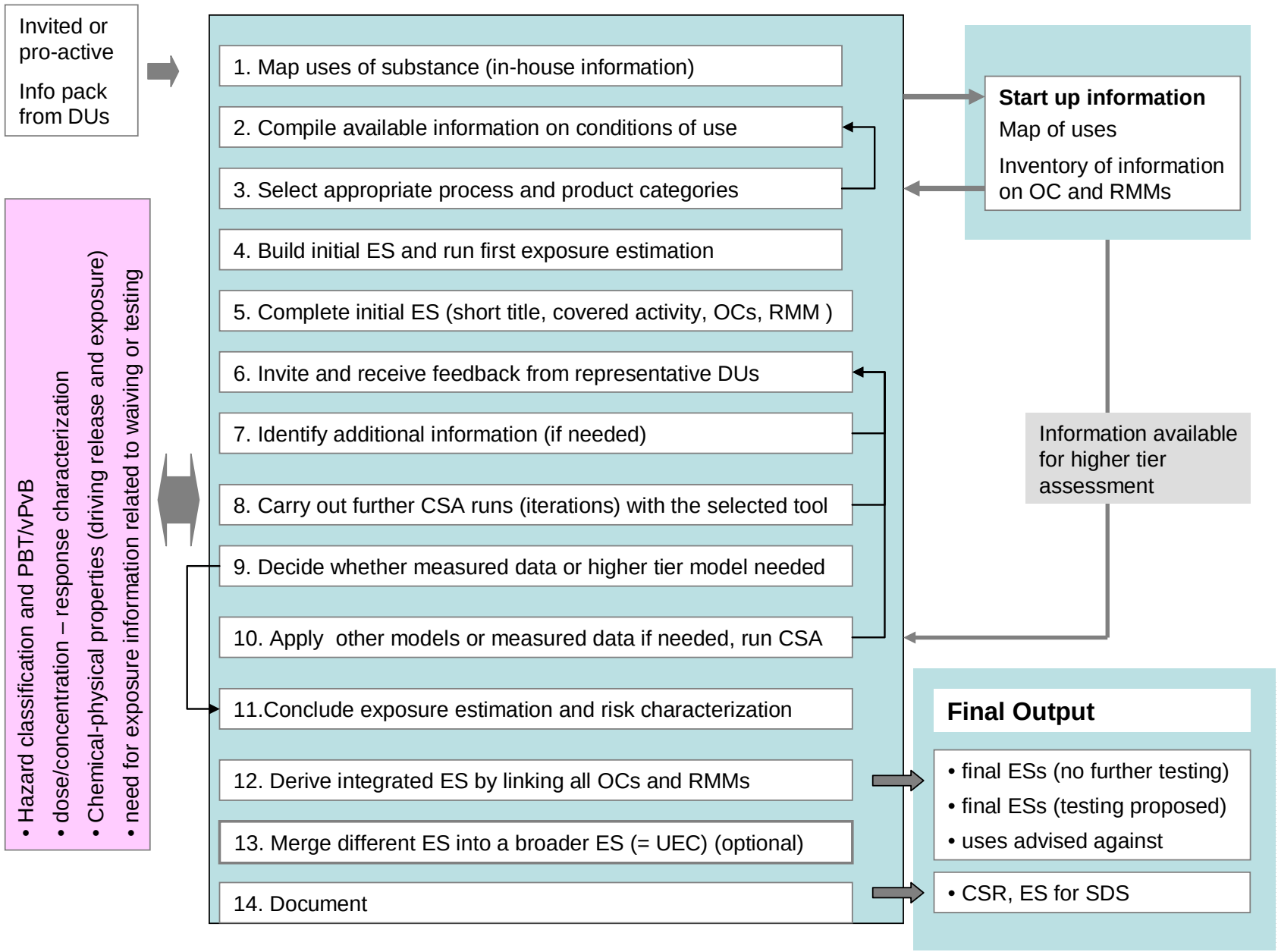
Guidance on Information Requirements and Chemical Safety Assessment



Info on intrinsic properties and hazard assessment



Workflow for generation of Exposure Scenarios



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Building Exposure Scenarios

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Initial Exposure Scenarios

- Short title
- Operational conditions (OC)
- Risk management measures (RMM)

If risks are not controlled

Decisions by M/I

- Refine hazard assessment
- Refine exposure estimate
- Modify RMM or OC
- Advise against use

Final Exposure Scenarios

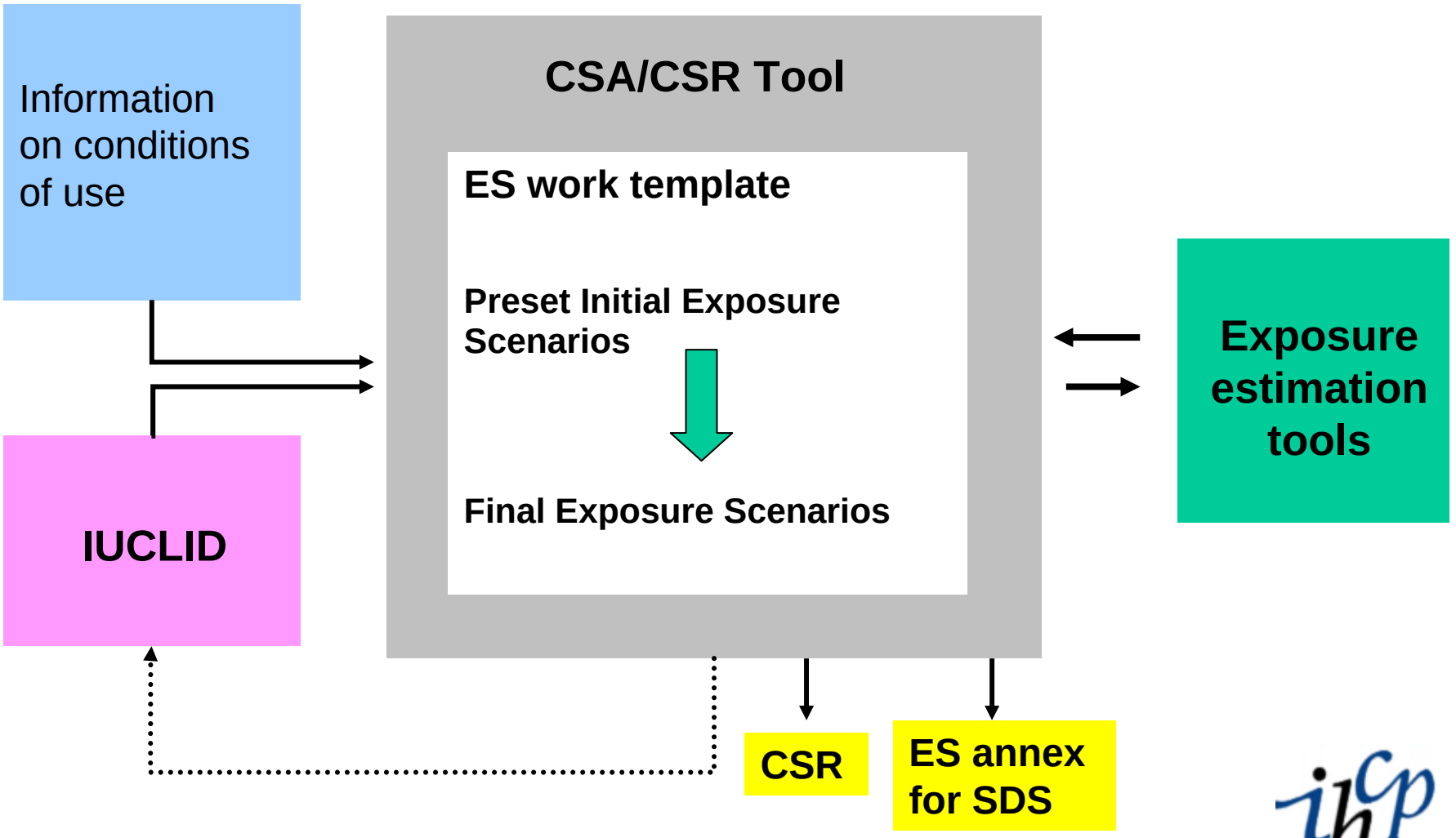
- Short title
- Operational conditions (OC)
- Risk management measures (RMM)

IT tools for developing ES, conducting CSA and preparing CSR

- "Analysis and Design" study April 2007 – March 2008
  - Based on the outcome of RIP 3.2
  - Strong focus on Exposure Scenarios
  - Existing exposure estimation models and tools are taken into account
    - Challenge is that existing tools do not normally (transparently) include or describe how Operational Conditions and Risk Management Measures are included
    - -> Further development needed to make tools REACH compliant

- ECHA is currently preparing a call for tender for building the 1st generation of CSA-CSR tool
  - CSR template (1 June 2008)
  - IUCLID plug in for CSR generation (summer 2008)
  - First version of ES/CSA/CSR tool (2009)

IT tools for developing ES, conducting CSA and preparing CSR



Conclusions – 1

REACH Registration

- Manufacturers and importers
- Obtain/generate information on their substances and
- Use this knowledge to enable well-informed management of the risks that substances may cause throughout their life cycle
- Cooperation with Downstream Users

Conclusions – 2

- Exposure scenarios play a very important role by giving use conditions for controlling risks
- Exposure Scenarios are:
  - developed in the *iterative* Chemical Safety Assessment (CSA)
  - recorded/documented in the Chemical Safety Report (CSR)
  - communicated to downstream users as annexes to Safety Data Sheets (SDSs)
- Managing risks becomes an integral part of the Chemical Safety Assessment (new mindset!)
- Communication between DU and M/I should take place before registration.
- Guidance: (Soon) available via ECHA web-site
- Supporting IT tools and examples: Under development

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Thank you for your attention !